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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,387	12/04/2001	Pawan Seth	8674-000011	6995

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EXAMINER
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SPEAR, JAMES M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/005,387

**Applicant(s)**

SETH, PAWAN

**Examiner**

James M Spear

**Art Unit**

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-15,17-20,22-47 and 49-56 is/are rejected.
- 7) ☒ Claim(s) 3,16,21 and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Claims 1, 2, 4-15, 17-20, 22-47, and 49-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the water soluble polymer, does not reasonably provide enablement for any water soluble polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. When considering the factors relating to *In re Wands*, as set forth in applicant's response it is the position of the examiner that the specification is only enabling for the particular water soluble polymer polyvinylpyrrolidone. While applicants state with regard to Breadth of the Claims the overall scope of the claims is relatively limited, reciting the broad disclosure of water soluble polymers in fact unduly broadens the claims. "An applicant is entitled to claims as broad as the prior art and his disclosure will allow". *In re Rasmussen* 211 USPQ 323 (1981) The disclosure describes extended release tablets wherein the coating modifies the release. To suggest that without limit any water soluble polymer can be used, by claiming such presents claims which are not commensurate in scope with the disclosure. The Nature of the Invention which relates to using polymer coatings to modify dissolution profiles is known as applicant has pointed out. The polymers as disclosed are critical. "Claims which fail to recite a feature described as critical to obtain the desired result are not supported by the enabling disclosure". *In re Mayhew*, 188 USPQ 356. Since there is no evidence of every water soluble polymer being effective in the coating, claims which do not recite the particular polymer polyvinylpyrrolidone are not supported by the disclosure.

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2. The State of the Prior Art may describe suitable membrane materials, however there is no evidence of such disclosed in applicant's disclosure.

3. As for the Level of Ordinary Skill in the Art, the question is not what the skilled artisan is aware of but what is disclosed in the application. No evidence is presented for a means of determining or distinguishing between the numerous known polymers and what would be enabled in the claimed composition.

4. While it may be predictable which polymers would be soluble in water based on the knowledge of a person skilled in the art, the disclosure only list polyvinylpyrrolidone. To make an accurate prediction it is believed that properties other than solubility should be evident. None are disclosed.

5. The Amount of Direction Provided by the Inventor, The Existence of Working Examples and The Quantity of Experimentation Needed to Make or Use the Invention Based of the Content of the Disclosure all relate back to the fact that the disclosure is limited to a single species. No means of comparing other suitable water soluble polymers is disclosed. Distinguishing common characteristics, properties, or features are not evident. The specification only provides support for the water soluble polymer polyvinylpyrrolidone.

6. Claims 1, 2, 4-15, 17-20, 22-47 and 49-56 are rejected.


7. Claims 3, 16, 21 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 703 308 2457. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on (703) 308 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.

  
James M Spear  
Primary Examiner  
Art Unit 1615

November 3, 2003